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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,376	07/28/2001	Shi-You Ding	NREL 01-36	9956

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[REDACTED] EXAMINER

SWOPE, SHERIDAN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1652

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/917,376	DING ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 December 2002.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15,28-36 and 43 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-15,28-36 and 43 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 28 July 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicant's response, on December 26, 2002, Paper No. 13, to the first Office Action on the Merits of this case is acknowledged. It is acknowledged that applicants have amended Claims 1, 3-13, 15, 28, 29, and 33 and added Claim 43. Claims 1-15, 28-36, and 43 are hereby considered on their merits.

Specification

The specification was previously objected to as failing to teach the consensus sequences for the GH74 catalytic domain of cellulases. Applicants state that the required teachings are provided in Tables 3, 4, and 5. Tables 4 and 5 are not relevant to the issue. Table 3, by comparing AviIII to the catalytic domain of AvicelaseII, provides evidence that AviIII has 45% identity to AvicelaseII. However, whether the amino acids residues conserved between AviIII and Avicelase II contain the consensus sequence for a GH74 catalytic domain can not be deduced by comparison of AviIII with a single protein. A consensus sequence for any protein motif or domain is deduced by comparing all members of a class of proteins having the same biological function (see for example Hanks et al, 1991 Fig 1, pgs 46-47). Such analysis teaches those amino acid residues that must be conserved to maintain the biological function of the domain as well as those residues that can be modified with no change to function. In addition, such data allows classification of new proteins as having, or not having, said functional domain. Therefore, objection to the specification because it fails to define the motif or conserved sequence by which the GH74 domain can be identified is maintained.

Claim Rejections - 35 USC § 112 First Paragraph

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Rejection of Claims 1-9, 14, 15, 28-36, and 43 under 35 U.S.C. 112 first paragraph for lack of enablement is maintained. Rejection of Claims 1-9, 14, and 15 under 35 U.S.C. 112 first paragraph for lack of written description is maintained. The detailed reasons for rejection of Claims 1-9, 14, 15, 28-36, and 43 under 35 U.S.C. 112 first paragraph is described in the prior action.

Claims 1, 14, and 15 were rejected because the specification does not support the scope of the claims, which encompasses any composition comprising any thermo-stable AviIII polypeptide having a GH74 domain. Applicants traverse the enablement rejection stating that, Example 2 and Table 3 on pages 32-33 of the specification provide knowledge and guidance as to which amino acids are tolerant of modification as well as those that are conserved and presumably not subject to modification. This argument is not found to be persuasive. Example 2 and Table 3 provide evidence that AviIII contains a catalytic domain that is homologous to the GH74 domain of AvicelaseII. These data support the utility of AviIII as an endoglucanase. However, these data do not teach which specific amino acid residues of AviIII and AvicelaseII represent the conserved sequence for a GH74 domain. Example 2 and Table 3 also do not teach which changes can be tolerated in AviIII's amino acid sequence and still maintain the desired GH74 cellulase activity since, as state above, the identity of the consensus sequence for a GH74 domain is not taught. In addition, Example 2 and Table 3 do not teach which changes can or cannot be tolerated for maintenance of AviIII's thermo-stability since AvicelaseII is not a thermo-stable enzyme. Example 2 and Table 3 do not provide a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired GH74 activity and

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thermostability, as recited, and the specification provides insufficient guidance as to which of the essentially infinite possible choices of modified sequences is likely have the desired utility.

Rejection of Claims 2-9, 28-36, and 43 is also maintained for the reasons described above.

Rejection of Claims 1-9, 14, and 15 as well as Claims 28-36 and 43 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention is maintained. This rejection was explained in the previous Office Action. Applicants argue that the specification teaches a working embodiment and how to create functionally similar compositions by identifying and comparing highly conserved sequences in Example 2 and Table 3 and, thus, no lack of enablement has been established. First it should be noted that the instant rejection is for lack of a sufficient written description, not for lack of enablement. As previously explained the single working embodiment is not representative of the claimed genus. As previously explained the current claims recite a genus, which is highly variable in structure and function, such that the single disclosed species is not representative of the claimed genus.

For these reasons, and those detailed in the prior action, rejection of Claims 1-9, 14, 15, 28-36, and 43 under 35 U.S.C. 112 first paragraph is maintained.

Claim Rejections - 35 USC § 103

Rejection of Claims 1-13, 28, and 29 under 35 U.S.C. 103(a) as being unpatentable over Mohagheghi et al, 1986 in view of Berghem et al, 1976 and Katz et al, 1968 is maintained. The rejection was explained in the previous Office Action. Applicants argue that motivation to

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isolate a cellulase from *Acidothermus celluloyticus* is not provided by Katz et al is “nothing more than generalized finger-pointing towards a desirability of isolating additional cellulases, and it utterly fails to address identification of the specific cellulase now being claimed”. This argument is not found to be persuasive. Katz et al, was cited as demonstrating that elevated temperatures enhance the susceptibility of cellulose to degradation (Paper No. 11, pg 11, lines 11-12). Therefore, it would be obvious to a person of ordinary skill in the art to isolate a thermostable cellulase from *A. celluloyticus*, which could be used for degrading cellulose during the treatment of fabric at elevated temperature.

Applicants also argue that “nothing can be deduced from the isolation of cellulase from *Trichoderma viride* which would lead those skilled in the art to deduce that the GH74 family cellulase with features now being claimed could be isolated from *A. celluloyticus*”. This argument is not found to be persuasive. To isolate their cellulose from *T. viride*, Berghem et al teach an enzymatic cellulase assay using acid-swollen Avicel, a microcrystalline cellulose, as a substrate (pg 623, parg 2, lines 1-9; Figs 1-6). This assay could also be used to isolate the cellulase of the instant application as evidenced by the fact that endoglycanases (Irwin et al, pg 1710, parg 8, line 4; Table 1) as well exoglycanases (Avicelase II from the thermophilic bacteria *Clostridium stercorarium*; Bronnenmeier et al, 1991; pg 380 parg 5) can degrade Avicel. Therefore, Berghem et al teach an assay that would have utility in analyzing the activity of the cellulase of the instant application during biochemical purification. Berghem et al also teach that cellulases can be purified using molecular sieve chromatography, chromatography on a dipolar adsorbent, isoelectric focusing, and affinity chromatography on an Avicel column (pg 622, parg 2-8). Affinity chromatography on an Avicel column would be a very powerful method for

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isolating the cellulase of the instant application as, it was well known in the art that exoglucanases bind to cellulose resin (Tan et al, 1986; pg 259, parg 3, lines 16-20; Fig 4). It would be obvious to a person of ordinary skill in the art to use the Avicel chromatography method as well as a combination of molecular sieve chromatography, chromatography on a dipolar adsorbent, and/or isoelectric focusing to isolate the cellulase of the instant application. Therefore, rejection of Claims 1-13, 28, and 29 under 35 U.S.C. 103(a) as being unpatentable over Mohagheghi et al, 1986 in view of Berghem et al, 1976 and Katz et al, 1968 is maintained.

Specification

The specification is objected to because: (i) the Tables are not in the order presented; (ii) Table 4 doesn't agree with the sequence listing in stating that the CBD begins at Valine859; and (iii) on page 17 line 12-13, the Tomme and Claeysens, 1989 reference is not correct.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 8:30-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan Lee Swope



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